PATENT
Docket No. 293.00010102

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Daryll A. EMERY et al.	)	Group Art Unit: 1655
Serial No.:	10/749,602	)	Examiner: Patricia A. Leith
Confirmation No.:	8548	)	
Filed:	31 December 2003	)	
For:	IN OVO DELIVERY OF AN IMMUNOGEN CONTAINING IMPLANT	)	

DECLARATION UNDER 37 C.F.R. §1.132

Assistant Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I, Daryll A. Emery, declare and say as follows:

1. I received my B.S. in Microbiology and in Community Health from Mankato State University (Mankato, Minnesota) in 1976, my M.S. in Veterinary Microbiology from the University of Minnesota (St. Paul, Minnesota) in 1989, and my Ph.D. from the Department of Veterinary Pathobiology in Veterinary Microbiology, University of Minnesota, in 1993. I was Director of Research at Willmar Poultry Company Inc. (Willmar, Minnesota), from 1991 to 2002. I have been Director of Research at Epitopix, LLC (Willmar, Minnesota) since 2002. While Director of Research at both Willmar Poultry Company and Epitopix I conducted research directed to identifying vaccines to protect animals from infection by gram negative and gram positive microbes and methods for delivering vaccines to animals.

2. I am an inventor of the above-identified patent application. I am also an inventor of Emery et al. (U.S. 5,830,479), a document cited in the rejections under 35 U.S.C. §§ 103(a) in the Office Action dated May 1, 2005.

3. I have read and am familiar with the contents of the Office Action dated November 15, 2006, and I make this Declaration in support of the patentability of the claims of the above-identified patent application.

4. The Office Action makes specific reference to Example 3 of Emery et al. In Example 3 of Emery et al., seventy-two turkey poults were used in a vaccination trial to evaluate a siderophore receptor protein vaccine. At the time of this experiment, the breeder hens used as the source of the eggs were vaccinated to protect against the following: Newcastle disease, hemorrhagic enteritidis, fowl cholera, avian encephalomyelitis and fowl pox, Avian Para Influenza, Avian Influenza H1N1, Erysipelothrix, and Salmonella. The Salmonella used for vaccination were killed whole cell bacterins, where the cells were grown in conditions that included iron. Since the Salmonella were grown in conditions that included iron, the Salmonella did not express iron regulated siderophore receptor proteins. The breeder hens had not been vaccinated with the siderophore receptor protein vaccine. Thus, these breeder hens did not have any antibody made in response to the siderophore receptor protein vaccine. Since the breeder hens did not have this type of antibody, the eggs they laid could not have had maternal antibody made in response to the siderophore receptor protein vaccine, and the poults hatching from the eggs and used in the trial did not have this type of maternal antibody.

5. It would be readily apparent to a person knowledgeable in the testing of vaccines in birds that the poults used in Example 3 of Emery et al. did not have maternal antibody to the vaccine being evaluated. It is well known that immunizing animals, including poults, with an antigen when maternal antibodies to the antigen are present is not desirable. The presence of maternal antibodies to the immunizing antigen can prevent the development of an active immune response to the antigen. This phenomenon is often referred to as maternal antibody interference or maternal antibody blocking. A person knowledgeable in the testing of vaccines would recognize that the use of eggs with maternal antibody to the vaccine would influence the experiment. For instance, if a vaccine were administered to poults with maternal antibody to the immunizing composition the immune response could be compromised, and it would not be possible to determine why there was no immune response. The skilled person could not

differentiate between maternal antibody interference and immunogenicity of the composition.

6. The Office Action states that according to Sharma, a bird's immune response is elicited even in the embryonic stage when vaccinated in-ovo. Sharma states that the flock used as the source of embryonated eggs was free of exposure to HVT and several other pathogenic agents (see Sharma at col. 4, lines 25-34). Since the flock used as the source of embryonated eggs was free of exposure to HVT, the breeder hens did not have antibody to the HVT present in the vaccine. Since the breeder hens did not have antibody to the HVT present in the vaccine, the eggs laid by those breeder hens could not have had maternal antibody to the HVT.

7. I respectfully submit that the above evidence establishes that the Examiner's interpretation of Emery et al. and Sharma is not correct. As a result, several statements made by the Examiner should be reconsidered. For instance, at page 10 of the Office Action the Examiner states "sustained delivery of a siderophore receptor from a gram-negative bacterium until 21 days post-hatch would have also elicited a positive immune response in the bird because Emery et al. clearly taught immunization at day 21 of post-hatch with positive immune responses." Sustained delivery of a siderophore receptor from a gram-negative bacterium until 21 days post-hatch would not necessarily result in a positive immune response in a bird that had maternal antibody to the siderophore receptor from a gram-negative bacterium. The maternal antibody would be expected to prevent the full development of an active immune response to the antigen.

8. I further declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent that issues thereon.

Date: 5.15.07 Signed: Daryll A. Emery

Daryll A. Emery